UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY)
AVERAGE WHOLESALE PRICE) MDL NO. 1456
LITIGATION) Civil Action No. 01-12257-PBS
) Hon. Patti B. Saris
THIS DOCUMENT RELATES TO)
CLASS 1 RESIDENTS OF THE)
COMMONWEALTH OF)
MASSACHUSETTS)
·)

DECLARATION OF ANDREW D. SCHAU

ANDREW D. SCHAU declares as follows:

- 1. I am a member of the law firm of Patterson Belknap Webb & Tyler LLP, attorneys for the J&J Defendants. I submit this declaration in support of the J&J Defendants' Post-Remand Motion for Summary Judgment Against Class 1 Residents of the Commonwealth of Massachusetts.
 - 2. Attached hereto are true and correct copies of the following exhibits:

Designation	Description	
Exhibit 1	Relevant excerpts from the transcript of the July 3, 2007 hearing in the above-captioned action.	
Exhibit 2	Findings and Order on Motion of Track 1 Defendants for the Entry of Judgment Pursuant to Federal Rule of Civil Procedure 54(b), dated November 20, 2007, in the above-captioned action.	
Exhibit 3	Notice of Appeal by Larry Young and Therese Shepley, dated December 19, 2007, in the above-captioned action.	
Exhibit 4	Order of Court, dated February 15, 2008, in <i>In re: Pharmaceutical Industry Average Wholesale Price Litigation</i> , No. 08-1002 (1st Cir.)	

Designation	Description
Exhibit 5	Relevant excerpts from the transcript of the October 8, 2009 hearing in the above-captioned action.
Exhibit 6	Relevant excerpts from the Declaration of Raymond S. Hartman in Opposition to Defendants' Motions for Summary Judgment, dated April 6, 2006, in the above-captioned action.
Exhibit 7	Relevant excerpts from the November 27, 2006 transcript of the Class 2 and Class 3 trial in the above-captioned action.
Exhibit 8	Relevant excerpts from the November 21, 2006 transcript of the Class 2 and Class 3 trial in the above-captioned action.
Exhibit 9	Relevant excerpts from the November 20, 2006 transcript of the Class 2 and Class 3 trial in the above-captioned action.
Exhibit 10	Relevant excerpts from the transcript of the June 24, 2004 hearing in <i>United States v. MacKenzie</i> , CR-01-10350-DPW (D. Mass.).
Exhibit 11	Relevant excerpts from the November 7, 2006 transcript of the Class 2 and Class 3 trial in the above-captioned action.
Exhibit 12	Relevant excerpts from the November 9, 2005 deposition of Larry Young.
Exhibit 13	Relevant excerpts from the November 11, 2005 deposition of James Shepley.
Exhibit 14	Relevant excerpts from the December 11, 2006 transcript of the Class 2 and Class 3 trial in the above-captioned action.
Exhibit 15	Relevant excerpts from the November 29, 2006 transcript of the Class 2 and Class 3 trial in the above-captioned action.

I declare under penalty of perjury that the foregoing is true and correct.

/s/ Andrew D. Schau
Andrew D. Schau Dated: November 23, 2009

CERTIFICATE OF SERVICE

I certify that on November 23, 2009 a true and correct copy of the foregoing was delivered via electronic service to all counsel of record pursuant to Case Management Order No. 2.

/s/ Andrew D. Schau

Andrew D. Schau

EXHIBIT 1

Page 1

UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

IN RE:

PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE

LITIGATION

Civil Action No. 01-12257-PBS Courtroom No. 19 1 Courthouse Way Boston, MA 02210 10:00 a.m., Tuesday

July 3, 2007

HEARING

THE HONORABLE PATTI B. SARIS, UNITED STATES DISTRICT JUDGE

APPEARANCES:

Hagens Berman Sobol Shapiro LLP, (by Steve W. Berman, Esq.) 1301 5th Avenue, Seattle, WA 98101-1090, on behalf of the Plaintiffs.

Hagens Berman Sobol Shapiro LLP, (by Edward Notargiacomo, Esq.), One Main Street, Cambridge, MA 02142, on behalf of the Plaintiffs.

The Haviland Law Firm, LLC, (by Donald E. Haviland, Esq.) 740 S. Third Street, Philadelphia, PA 91912, on behalf of the Plaintiffs.

Hogan & Hartson, (by Steven J. Edwards, Esq. and Lyndon M. Tretter, Esq.), 875 Third Ave., New York, NY 10022, on behalf of the Defendant Bristol-Myers Squibb.

> Marie L. Cloonan Federal Court Reporter 1 Courthouse Way - Room 7200 Boston, MA 02210- 617-439-7086 Mechanical Steno - Transcript by Computer

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Page 8
 1
       just had totally gone from my mind. Although, Schering
 2
       quite quickly reminded me of it.
 3
                  So, there will be no more trials with respect
       to the first five defendants in Track 1 with respect to,
 5
       as I understand it, Class 1. And, then, we've got the
       two -- what I'll call -- bellweather trials on Classes 2
       and 3. And, I know you're eager to schedule a national
       class, but I'm just as eager to start going into
 9
       Class -- Track 2.
10
                  So, I might schedule them for a hearing. And,
11
       I know -- I see Mr. DeMarco here. We've got to move
12
       that because it interferes with some people's vacation
13
       plans to --
14
                  What date was it?
15
                  MR. DE MARCO: July 17th, your Honor.
16
                  THE COURT: July 17th.
17
                  THE CLERK:
                             2:30 p.m.
18
                  THE COURT: But, as far as Track 1 goes --
19
                  MR. BERMAN:
                                There's one issue on Track 1,
20
       your Honor.
21
                  THE COURT:
                             Yeah?
22
                  MR. BERMAN: And, that is Johnson & Johnson.
23
       I know that you said that their drugs didn't exceed the
24
       30 percent rule for the purposes of Class 2 and 3. But,
25
       it's our position -- and we would like the opportunity
```

Page 9 1 to present this or maybe you've already decided -- that 2 that 30 percent would not apply to Track 1. I thought I ruled that. The 30 3 THE COURT: percent did apply to Track -- to Class 1. 5 Well, you have a footnote that MR. BERMAN: talks about -- implies that, but you did not rule in That's your ruling, that we have no J & J that way. 8 Class 1 trial. 9 I thought it was not a footnote. THE COURT: I thought I went on and on about it. I think I went on 10 11 and on about everything. So, maybe I ought to look at 12 it again. 13 MR. BERMAN: I don't think you did --14 I think I said that I rejected THE COURT: plaintiffs' position that the per se liability for Class 15 1 and that I thought that the 30 percent speed limit 16 should apply to Class 1 as well. And, that would be, I 17 18 thought applicable to all of the defendants. 19 So, why is that not clear? 20 MR. BERMAN: Well, I didn't see that in the 21 order, your Honor. 22 THE COURT: They've got it. 23 MR. BERMAN: At the time we negotiated the --24 via that settlement, both sides thought that was a risk that could go either way. And, we discussed that with 25

Page 10 1 The mediator didn't think it was clear the mediator. 2 either. 3 THE COURT: Well --4 MR. BERMAN: It's clear now. 5 THE COURT: It's clear now. And, I will look 6 at it again. If it wasn't clear, it is clear. 7 percent speed limit applies to Class 1. 8 I rejected a per se position. And, I have to 9 go look through it again, because I thought it was 10 clear. That's why I essentially had the expert go back 11 and calculate the damages again. Because, the way he 12 did it was he aggregated all the years when he did it 13 with the 30 percent speed limit. He didn't back out 14 the -- it might have been statute of limitations and on 15 the specific NDCs. That's why I needed a root 16 calculation. 17 Otherwise, I could have done it. Right? On 18 the per se. Because, he did it year by year. 19 MR. BERMAN: Correct, you could have, yeah. 20 THE COURT: I could have done that. 21 22 MR. BERMAN: But, we felt it was a different 23 issue with the consumers, because there's no evidence

issue with the consumers, because there's no evidence that they had any knowledge of the so-called industry norm of 20, 25 percent.

24

25

Page 11 1 Well, I ruled to the contrary and THE COURT: I don't accept that position. And, I thought it was If not, I'm making it clear now. 3 Now, I want to know what -- I'm ready, at this 4 point, to deal with Montana and Nevada and move them back to their home states. I've waited because I 6 thought I would give someone the template so that 7 someone else wouldn't have to relive this entire piece of it. And, the question only is, from my point of view, whether or not you all want to talk to them about 10 -- before I ship it off -- whether it's worth using 11 Eric Green's expertise to try and settle it before I do 12 13 that or whether I should just send it. MR. BERMAN: From our perspective, your Honor, 14 we are already in discussion with some of the 15 16 defendants. So, if you want to get Mr. Green involved, the plaintiffs would not -- we think that's a good 17 18 idea. THE COURT: I know I've only got one of you 19 here and not everybody. But, what do you think? 20 I mean, once I've got a template, does this 21 I know I've got this Medicaid and it's not 22 make sense? 23 -- the TPPs and the Medicare statute. But, Mr. Green knows so much about it right now that I'd hate to ship 24 it back to the MDL and have them ship it up to the 25

EXHIBIT 2

UNITED STATES DISTRICT COURT DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL NO. 1456

THIS DOCUMENT RELATES TO 01-CV-12257

CIVIL ACTION NO. 01-12257-PBS

FINDINGS AND ORDER ON MOTION OF
TRACK 1 DEFENDANTS FOR THE ENTRY OF JUDGMENT
PURSUANT TO FEDERAL RULE OF CIVIL PROCEDURE 54(b)

November 20, 2007

Saris, U.S.D.J.

(];

Defendants AstraZeneca Pharmaceuticals LP ("AstraZeneca");
Bristol-Myers Squibb Company and Oncology Therapeutics Network
Corporation ("BMS"); Johnson & Johnson, Centocor, Inc. and Ortho
Biotech Products, L.P. (together "the J&J Defendants"); and
Schering-Plough Corporation, Schering Corporation and Warrick
Pharmaceuticals Corporation (together "Schering/Warrick") have
moved for the entry of judgment pursuant to Fed. R. Civ. P. 54(b)
(Docket No. 4880). Upon consideration of the motion and the
submissions of the parties, the Court ALLOWS the motion. In
accordance with Rule 54(b), the Court makes the following
findings. See Spiegel v. Trs. of Tufts Coll., 843 F.2d 38, 42-43
(1st Cir. 1988).

FINDINGS

This is a multi-district litigation ("MDL")
 consolidating a number of class actions that were brought against
 pharmaceutical manufacturers beginning in 2001. The actions,

as originally pleaded, included federal claims under the Racketeer Influenced and Corrupt Organizations Act ("RICO") and various state consumer protection statutes.

- 2. The essence of the claims was that Defendants caused various industry publications such as the Red Book, First DataBank and MediSpan to publish fictitious average wholesale prices ("AWPs"). These AWPs were used by Medicare and third party payors ("TPPs"), such as insurance companies, to reimburse doctors for physician-administered drugs, such as chemotherapy agents. Plaintiffs claimed that the AWPs were fictitious because they grossly exceeded the true average prices. Plaintiffs also claimed that each Defendant unlawfully marketed the 'spread' or difference between the AWP, the benchmark for reimbursement, and the actual acquisition price of the drugs paid by providers such as doctors and pharmacies.
- 3. In March 2004, the Court created a "fast track" consisting of five defendants or defendant groups: AstraZeneca, BMS, GlaxoSmithKline ("GSK"), the J&J Defendants and Schering/Warrick. The remaining defendants were placed in a "regular track" for discovery and trial. The fast track defendants became known as the "Track 1" defendants, and the remaining defendants became known as the "Track 2" defendants.
- 4. In January 2006, the Court certified three classes for trial against the Track 1 Defendants: (a) Class 1 -- consumers in

¹ The remaining defendants are Abbott, Amgen, the Aventis Group, Baxter, Bayer, Dey, the Fujisawa Group, Immunex, Pfizer/Pharmacia, Sicor and Watson.

- 40 states who made co-payments for drugs under Medicare Part B;

 (b) Class 2 -- TPPs in Massachusetts who made co-payments for drugs under Medicare Part B; and (c) Class 3 -- consumers and TPPs in Massachusetts who paid for drugs in non-Medicare transactions based on contracts expressly using AWP. Class 1 was not certified as to Schering/Warrick, because there was no class representative who had made a co-payment for a Schering or Warrick product under Medicare Part B. In re Pharm. Indus.

 Average Wholesale Price Litiq., 233 F.R.D. 229 (D. Mass. 2006) (class certification order).
- 5. By order dated November 2, 2006, the Court denied Plaintiffs' motion for partial summary judgment as to the Class 1 and Class 2 claims, and also denied the Track 1 Defendants' motions for summary judgment as to the Class 1 and Class 2 claims, except with respect to Medicare Part B drugs furnished in 2004. In re Pharm. Indus. Average Wholesale Price Litiq., 460 F. Supp. 2d 277, 288 (D. Mass. 2006). The Court also denied the Track 1 Defendants' motions for summary judgment on the Class 3 claims.
 - 6. GSK has settled the claims of all three classes.
- 7. A settlement of the Class 1 claims against AstraZeneca and BMS has been reached and awaits final approval of the Court.
- 8. The Class 2 and 3 claims against AstraZeneca, BMS, the J&J Defendants, and Schering/Warrick, alleging violations of Mass. Gen. Laws ch. 93A, proceeded to a bench trial before the Court in November of 2006. On June 21, 2007, the Court issued

Findings of Fact and Conclusions of Law holding AstraZeneca, BMS and Warrick liable with respect to certain drugs for certain time periods as set forth in the Court's opinion. <u>In re Pharm. Indus.</u>

<u>Average Wholesale Price Litig.</u>, 491 F. Supp. 2d 20, 109 (D. Mass. 2007). The Court hereby incorporates that opinion as if set forth fully herein.

- 9. In the same opinion, the Court dismissed all Class 2 and 3 claims against Schering. <u>Id.</u> at 108 09. The Court found no damages in Class 3 for Warrick. <u>Id.</u> at 109. The Court also dismissed the claims against the J&J Defendants. <u>Id.</u> at 109.
- 10. On August 27, 2007, the Court held an additional hearing on damages.
- 11. On November 1, 2007, the Court issued a Memorandum and Order on damages. In re Pharm. Indus. Average Wholesale Price Litig., No. 01-12257, 2007 WL 3225922 (D. Mass. Nov. 1, 2007). The Court found that AstraZeneca's conduct was knowing and willful as to Class 2 and awarded double damages as to AstraZeneca for Class 2. Id. at *3. The Court also found that BMS' conduct was knowing and willful as to Class 2 when "less than ten percent of its sales were made within 5% of the list price, and the spreads were huge," and thus awarded double damages as to Taxol for 2002, Cytoxan in 1999 and 2001, and Rubex in 1998 and 2002. Id. at *3-4. The Court found that neither BMS's nor AstraZeneca's conduct was knowing and willful as to Class 3 and accordingly did not award multiple damages as to Class 3. Id. at *4. The Court issued a final award of

damages and interest against AstraZeneca and BMS as follows:

	Class 2		Class 3	Overall
	Single Damages with Prejudgment Interest	Total Damages with Doubling	Single Damages with Prejudgment Interest	Total Award for Classes 2 and 3
AstraZeneca	\$3,467,267	\$5,557,370	\$7,384,499	\$12,941,869
BMS	\$309,267	\$388,557	\$307,037	\$695,594

Id. at *4 - 5.

- 12. As to Warrick, after considering further expert testimony, the Court found in its November 1, 2007 Order, that "Warrick has produced undisputed evidence that its unfair and deceptive conduct in inflating the AWP for albuterol did not cause Class 2 any damages because of the methodology for calculating Medicare reimbursement for multi-source drugs based on a median." Id. at *4. Thus, the Court ordered entry of judgment in favor of Warrick. Id. at *4.
- 13. As to the J&J Defendants, the Court ruled, among other things, that although J&J's conduct was troubling, it did not violate Mass. Gen. Laws ch. 93A, in part because the spreads on the J&J Defendants' subject drugs (Procrit® and Remicade®) never substantially exceeded the range of spreads generally expected by the industry and government. 491 F. Supp. 2d at 104. As a result, the Court ruled that the claims of Class 2 and Class 3 should be dismissed. Id. at 109. The claims by members of Class 1 are dismissed for the same reason.

14. Rule 54(b) provides, in pertinent part:

When more than one claim for relief is presented in an action . . . or when multiple parties are involved, the court may direct the entry of a final judgment as to one or more but fewer than all of the claims or parties only upon an express determination that there is no just reason for delay and upon an express direction for the entry of judgment.

Fed R. Civ. P. 54(b).

- 15. Here, there are no other claims between Plaintiffs and the J&J Defendants and Schering/Warrick. Accordingly, with respect to these parties, the judgments would have the requisite degree of finality.
- 16. Plaintiffs will be moving to certify nationwide classes for Classes 2 and 3 against BMS and AstraZeneca. However, there are no further claims against these companies under Massachusetts law.
- 17. For the reasons set forth below, the Court finds that there is no just reason to delay the entry of judgments with respect to the Track 1 Defendants.
- 18. There are no subsequent proceedings between the parties that threaten to moot the need for ultimate resolution of these issues in the Court of Appeals. Nor are there any issues with respect to the Track 2 defendants that will affect my decision with respect to the Track 1 Defendants.
- 19. Plaintiffs will not be prejudiced by the immediate entry of judgments against AstraZeneca and BMS pursuant to Rule 54(b); rather, if this Court's decision were to be affirmed, Plaintiffs

will benefit from having judgments capable of enforcement and distribution to class members prior to resolution of the Track 2 claims. There is no just reason to delay entry of judgments against Plaintiffs with respect to the claims against the J&J Defendants, and Schering/Warrick.

ORDER

IT IS THEREFORE ORDERED THAT:

Pursuant to Fed. R. Civ. P. 54(b), the Clerk shall enter judgments in the form of Appendices A through D as follows: in favor of Class 2 and Class 3 and against AstraZeneca in the amounts stated; in favor of Class 2 and Class 3 and against BMS in the amounts stated; in favor of Schering/Warrick and against Class 2 and Class 3; and in favor of the J&J Defendants and against Class 1, Class 2 and Class 3.

Dated: 11/20/07

S/PATTI B. SARIS
United States District Judge

7

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Case 1:01-cv-12257-PBS Document 4880-2 Filed 11/08/2007 Page 11 of 13

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY

AVERAGE WHOLESALE PRICE LITIGATION

THIS DOCUMENT RELATES TO

01-CV-12257-PBS AND 01-CV-339

Judge Patti B. Saris

Judgment

IT IS ADJUDGED AND DECREED THAT:

Judgment is entered in favor of Class 2 against Bristol-Myers Squibb Company in the amount \$388,557, including pre-judgment interest, and in favor of Class 3 against Bristol-Myers Squibb Company in the amount \$307,037, including pre-judgment interest, for a total of \$695,594.

Dated: November 2,2007

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Case 1:01-cv-12257-PBS Document 4880-2 Filed 11/08/2007 Page 12 of 13

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY

AVERAGE WHOLESALE PRICE LITIGATION

THIS DOCUMENT RELATES TO

01-CV-12257-PBS AND 01-CV-339

Judge Patti B. Saris

Judgment

IT IS ADJUDGED AND DECREED THAT:

Judgment is entered in favor of Schering-Plough Corporation, Schering Corporation, and Warrick Pharmaceuticals Corporation and against Class 2 and Class 3.

Dated: November 2007

Jan B Sans

Case 1:01-cv-12257-PBS Document 6667-1 Filed 11/23/09 Page 20 of 67

Case 1:01-cv-12257-PBS Document 4880-2 Filed 11/08/2007 Page 13 of 13

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL No. 1456

THIS DOCUMENT RELATES TO 01-CV-12257-PBS AND 01-CV-339

Civil Action No. 01-CV-12257 PBS

Judge Patti B. Saris

Judgment

IT IS ADJUDGED AND DECREED THAT:

Judgment is entered in favor of Johnson & Johnson, Centocor, Inc. and Ortho Biotech Products, L.P. and against Class 1, Class 2 and Class 3.

Dated: November 2007

12

Case 1:01-cv-12257-PBS Document 6667-1 Filed 11/23/09 Page 21 of 67
Case 1:01-cv-12257-PBS Document 4880-2 Filed 11/08/2007 Page 10 of 13

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY

AVERAGE WHOLESALE PRICE LITIGATION

THIS DOCUMENT RELATES TO

01-CV-12257-PBS AND 01-CV-339

Judge Patti B. Saris

Judgment

IT IS ADJUDGED AND DECREED THAT:

Judgment is entered in favor of Class 2 against AstraZeneca Pharmaceuticals LP in the amount \$5,557,370, including pre-judgment interest, and in favor of Class 3 against AstraZeneca Pharmaceuticals LP in the amount \$7,384,499, including pre-judgment interest, for a total of \$12,941,869.

Dated: November 2 12/007

Paus Davis

EXHIBIT 3

Case 1:01-cv-12257-PBS Document 6667-1 Filed 11/23/09 Page 23 of 67

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION

MDL No. 1456 C.A. No. 01-12257-PBS

THIS DOCUMENT RELATES TO: ALL ACTIONS

Judge Patti B. Saris

NOTICE OF APPEAL

Notice is hereby given that Larry Young and Therese Shepley, named representative plaintiffs in the above class action, appeal to the United States Court of Appeals for the First Circuit from the judgment entered against them on November 20, 2007, pursuant to Fed.R.Civ.P. 54(b), and from any and all orders antecedent and ancillary thereto, including, but not limited to, any and all interlocutory decrees, rulings, or opinions that merged into and became part of the judgment, that shaped the judgment, or upon which the judgment is based.

Respectfully submitted,

Dated: December 19, 2007

/s/ Donald E. Haviland, Jr.
Donald E. Haviland, Jr., Esquire
Adam S. Levy, Esquire, Of Counsel
Michael J. Lorusso, Esquire
THE HAVILAND LAW FIRM, LLC
740 S. Third Street, Third Floor
Philadelphia, PA 19147

Telephone: (215) 609-4661 Facsimile: (215) 392-4400

Counsel for Named Representative Plaintiffs, Larry Young and Therese Shepley

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Case 1:01-cv-12257-PBS Document 4954 Filed 12/19/2007 Page 2 of 2

CERTIFICATE OF SERVICE

I, Donald E. Haviland, Jr., hereby certify that on December 19, 2007, a true and correct copy of the foregoing Notice of Appeal was filed via ECF electronic filing and notice was sent to all counsel of record.

/s/ Donald E. Haviland, Jr.
Donald E. Haviland, Jr., Esquire
THE HAVILAND LAW FIRM, LLC
740 S. Third Street, Third Floor
Philadelphia, PA 19147
Telephone: (215) 609-4661

Facsimile: (215) 392-4400 haviland@havilandlaw.com

Counsel for Named Representative Plaintiffs, Larry Young and Therese Shepley

EXHIBIT 4

United States Court of Appeals For the First Circuit

No. 08-1002

IN RE: PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE LITIGATION.

ORDER OF COURT

Entered: February 15, 2008

This appeal is brought by two named plaintiffs, Larry Young and Therese Shepley, in their capacity as class representatives, from a judgment in favor of certain defendants ("the Johnson & Johnson defendants") in this massive antitrust class action. The Johnson & Johnson defendants have moved to dismiss the appeal because it is being prosecuted by The Haviland Law Firm ("Haviland"), which was recently disqualified as class counsel by the district court.

Plaintiffs, represented by Haviland, opposed the motion to dismiss, arguing that the appeal was filed prior to the disqualification order and that dismissing the appeal would deprive them of their right to appeal the allegedly erroneous judgment against them. Alternatively, plaintiffs asked that this appeal be consolidated with their appeal from the disqualification order.

Class counsel responded to the motion to dismiss by agreeing that Haviland can no longer prosecute this appeal but moving that the court permit class counsel to be substituted for Haviland rather than dismiss the appeal. In response to class counsel's motion, the Johnson & Johnson defendants acknowledged that class counsel are authorized to prosecute this appeal and that allowing class counsel's motion to substitute themselves for Haviland would make dismissal of the appeal unnecessary.

Although the disqualification order predated the notice of appeal, now that Haviland has been disqualified from serving as class counsel, it can no longer represent the class in this appeal. Further, although the disqualification order itself has been appealed, that order

^{&#}x27;Neither our jurisdiction to review that order nor the merits of that order are presently before us. Accordingly, we intimate no view on

presently remains in effect. Finally, although class counsel did not initially file an appeal on plaintiffs' behalf from the judgment in favor of the Johnson & Johnson defendants, now that class counsel have offered to take over prosecution of the appeal filed by Haviland, plaintiffs' right to pursue their appeal is no longer at stake. We therefore allow class counsel's motion to substitute themselves for Haviland in this appeal, thereby mooting the Johnson & Johnson defendants' motion to dismiss. Since allowing the motion to substitute makes the merits of the disqualification order irrelevant to this appeal, we deny plaintiffs' motion to consolidate this appeal with their appeal from the disqualification order.

Class counsel's motion to substitute is <u>granted</u>. Johnson & Johnson's motion to dismiss and plaintiffs' motion to consolidate are <u>denied</u>.

By the Court:

Richard Cushing Donovan, Clerk.

By: _____ Chief Deputy Clerk.

[cc: Steve Berman Esq., Rita Hanscom esq., Donald Haviland Esq., Steven Edwards Esq., Andrew Schau Esq., D. Scott Wise Esq., Jill Brenner Meixel Esq., Scott Kinsel Esq.]

either issue.

EXHIBIT 5

Page 1

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE:

CA No. 01-12257-PBS

PHARMACEUTICAL INDUSTRY AVERAGE

WHOLESALE PRICE LITIGATION

Pages 1 - 25

STATUS HEARING

BEFORE THE HONORABLE PATTI B. SARIS UNITED STATES DISTRICT JUDGE

United States District Court 1 Courthouse Way, Courtroom 19 Boston, Massachusetts October 8, 2009, 4:10 p.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 7200
Boston, MA 02210
(617)345-6787

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Page 7
                MR. SCHAU: You had certified a national class for
 1
 2
     Class 1.
 3
                MR. BERMAN: For Class 1 you had a national class
     without --
 4
 5
                THE COURT: Well, I had no intent to dismiss it
     other than for Massachusetts. Let's put it this way:
 6
     one was more surprised than I. Maybe the language went in
 7
     too fast or whatever. But I did intend for Massachusetts.
 8
     I couldn't have possibly thought through the country because
 9
     at that point I hadn't gone through all the national laws.
10
11
     So I did it under 93A was my intent. And if I was negligent
     in how I phrased it, I think I just took your wording, and I
12
13
     just didn't intend that, I didn't write on it. But I did
     intend it for 93A. So where does that leave us?
14
                MR. BERMAN: Well, I think, as I interpret the
15
     First Circuit opinion, because Class 1 was not -- there was
16
17
     no Class 1 93A trial, and they have a right to a jury, I'm
     not sure that your decision is binding. I mean, we never
18
19
     presented Class 1 --
20
                THE COURT: I thought 93A you don't get a right to
21
     a jury.
22
                MR. BERMAN: You don't get a jury, okay.
                THE COURT: So let's just back up a little. So it
23
     came up in about ten minutes at the tail end of the case.
24
     My intent was that under 93A, that it wouldn't fly.
25
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EXHIBIT 6

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

IN RE PHARMACEUTICAL INDUSTRY AVERAGE WHOLESALE PRICE)) MDL No. 1456
LITIGATION) CIVIL ACTION: 01-CV-12257-PBS
THIS DOCUMENT RELATES TO) Judge Patti B. Saris
01-CV-12257-PBS AND 01-CV-339) Chief Magistrate Judge Marianne B. Bowler
) [FILED UNDER SEAL PURSUANT TO COURT ORDER]

DECLARATION OF RAYMOND S. HARTMAN
IN OPPOSITION TO
DEFENDANTS' MOTIONS
FOR SUMMARY JUDGMENT

motions, if those specific issues involve matters of economic theory and fact that have not been developed in the related supporting expert declarations.

3. This Declaration proceeds as follows. In Section II, I identify the issues raised and arguments made by Defendants' motions and Defendants' experts. I discuss the reasons why these issues are irrelevant and why the Defendants' arguments fail. In Section III, I present additional detail for selected issues discussed in Section II. I also address selected data concerns raised by Defendants' experts in Section III. My conclusions are summarized in the Executive Summary above. Attachment A identifies materials cited in this Declaration.

II. Incorrect Assertions Made by Defendants and the Incorrect Analytic Results Put Forward by Defendants' Experts to Support those Assertions

4. In this Section, I introduce the assertions made and issues raised by Defendants through the three venues they have used: their Joint Motion for Summary Judgment; the specific individual motions for summary judgment filed by each of the Track 1 Defendants and the declarations put forward by their experts. I focus upon those assertions with economic content.⁴

A. Defendants Incorrectly Argue that Plaintiffs Argue that AWP should Equal ASP

5. Track 1 Defendants erroneously assert that Plaintiffs believe that "AWP should equal ASP." This is a serious mischaracterization of my testimony at this stage of the litigation. In all analyses put forward in my Affirmative and Rebuttal Declarations in

for Summary Judgment As to Class 1 and Class 2 (*Dukes Declaration*); Merits Report and Declaration of Gregory K. Bell, Ph.D., for the Bristol-Myers Squibb Group (*Bell Declaration*); the Declaration of Sumanth Addanki, Ph.D., for the Schering-Plough Group (*Addanki Declaration*); all *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257, March 15, 2006.

It is unclear what Dr. Addanki is talking about. That is not the alleged AWP inflation scheme. The allegations are laid out clearly in my September 3, 2004 Declaration in Support of Class Certification, as cited below in footnote 6. Also, see Section IV of the Third Amended Master Consolidated Class Action Complaint, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257, October 17, 2005, beginning at page 42.

⁴ My expertise as an economist does not allow me to address assertions regarding questions of law, such as the prevailing statute of limitations, whether the named Plaintiffs are adequate representatives of the relevant Classes and whether the federal government was deceived, as a matter of law.

⁵ See Section I heading, *Joint Motion*, page 9. In making this assertion, Defendants apparently draw upon the confused and frequently incorrect Declaration of Dr. Addanki. Dr. Addanki certainly does not comprehend the allegations in this matter. For example, he states at ¶ 17 of his Declaration, "The Complaint alleges a scheme in which the measure of the average *wholesale* price has been manipulated, i.e., that the AWP does not, in fact, represent what *wholesalers* obtain from providers and other intermediaries. The price received by the *manufacturers* has no bearing on this alleged manipulation."

Support of Class Certification and in my December 15, 2005 Declaration on Liability and Calculation of Damages, I have never taken the position that Defendants should have set the "AWP equal to the ASP." At all places in my Declarations, I have made explicit the following industry practice and knowledge: AWP has been a "sticker price" or "list price" for all drugs (by NDC); other list prices, most importantly WAC, are related formulaically to and are less than the AWP (AWP > WAC); transactions prices (including AMP and ASP) are negotiated off AWP and are less than AWP and WAC.⁶ I have articulated this same position in my most recent deposition.⁷

- 6. My formulaic methodology is straightforward.
 - The AWP has been taken by the industry, including the public and private sectors, to be *a signal* for transactions prices (EAC and ASP), particularly the acquisition costs of providers of Part B drugs.⁸
 - It is understood that the signal is not perfect, but it has been taken to be sufficiently accurate for reimbursement, despite its imperfection. Defendants' Expert Mr. Young has made this clear.⁹
 - While imperfect, prior to the AWP inflation scheme, the signal provided the expectation that the AWP of single-source physician-administered drugs exceeded the provider acquisition cost (EAC or ASP) by 15-25%.
 - Using the threshold of 30%, the formulaic methodology put forward in my December 15, 2005 Declaration finds AWP inflation subject to liability when the revealed spread ((AWP-ASP)/ASP) exceeds 30%.
 - Once actual spreads are found to exceed 30%, the related AWP is found to have been inflated to an extent not fully understood by public and private sector payers. Hence, those public and private payers could not and did not adequately respond to adjust their reimbursement practices to the AWP inflation scheme.
 - If I find liability (a spread in excess of 30%), I calculate damages. The Medicare damages are set forth by statute explicitly and without ambiguity.

⁶ See, for example, the September 3, 2004 Declaration of Raymond S. Hartman in Support of Class Certification, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, United States District Court, District of Massachusetts, MDL No. 1456, Civil Action No. 01-12257, ¶ 30. It has been understood that providers acquire such drugs at somewhat less than WAC. See also, my September 3, 2004 Declaration, Attachment D, ¶ 2, and my December 16, 2004 Rebuttal Declaration, ¶ 15, Section D.

⁷ Deposition of Raymond S. Hartman, *In re: Pharmaceutical Industry Average Wholesale Price Litigation*, February 27, 2006, pp. 670 – 686.

⁸ See pp. 9-10 of my September 3, 2004 Declaration in Support of Plaintiffs' Motion for Class Certification. See also Chapter 9, "Medicare payments for outpatient drugs under Part B" of Medicare Payment Advisory Commission (MedPAC), Report to the Congress: Variation and Innovation in Medicare, June 2003, which notes: "Most private payers are still using AWP-based payment methods similar to the Medicare model" (p. 164).

⁹ See ¶ 33 and Attachment K of my December 15, 2005 Declaration on Liability and the Calculation of Damages in this matter.

- Reimbursement is to be at "the lower of the EAC¹⁰ or the AWP" (or 95% of AWP over 1998-2003 or 85% of AWP over 2004; see footnote 13 of my December 15, 2005 Declaration).
- Under Medicare Part B reimbursement, Plaintiffs do not assert that the AWP should = ASP. It is clear by the liability threshold and by an understanding of the markets in question, that such an equality does not (nor are Plaintiffs suggesting that it should) occur. However, under Medicare Part B, reimbursement should be set at the lower of the AWP (or a percentage thereof) and the EAC = ASP, so that if liability is demonstrated and reimbursement is paid at x%*AWP, calculation of damages is determined directly by Statute.
- 7. Furthermore,, Defendants erroneously argue that "a finding that AWP was intended to mean ASP would impose liability on virtually every Medicare Part B eligible drug."

Since I never assumed that AWP "means" or "equals" ASP, my December 15, 2005 Declaration on Liability and Calculation of Damages finds and imposes no liability for any Medicare Part B drug whose spread of AWP relative to its ASP is not inflated, that is, did not exceed the liability threshold of 30%. ¹²

If, however, the spread is excessive (> 30%), I do find liability. At that point I assess damages according to the Medicare Statutes; that is, I measure damages as the amount by which the AWP (or the relevant percentage thereof) exceeds EAC = ASP. The assumption underlying this method is that had HCFA and Medicare understood sufficiently 13 the general extent to which the actual spreads on physician administered drugs were mega-spreads, they would have more aggressively undertaken the surveys to calculate EACs and impose the lesser of AWP (or a percent thereof) and the EAC practice for reimbursement.

8. Defendants continue their distorted characterization of Plaintiffs' position, stating, "Plaintiffs' proposed construction of the regulation [i.e., AWP = ASP] is entirely inconsistent with HCFA's interpretation of the regulation. Between 1992 and 1997, HCFA did not implement reimbursement on the basis of EAC, but rather reimbursed providers for physician-administered drugs at 100% of AWP." 14

¹⁰ Attempts to assert that the "actual charge" differ from the EAC (for 1998-2003) fail for reasons discussed in my December 15, 2005 Declaration on Liability and the Calculation of Damages, footnote 14.

¹¹ Joint Motion, pp. 1-2.

¹² See my December 15, 2005 Declaration on Liability and Calculation of Damages, ¶¶ 56-60. In my February 3, 2006 Supplemental Declaration on Liability and Calculation of Damages, I was asked to calculate damages under Medicare Part B reimbursement, if as a matter of law, it was determined that reimbursement rates for all Part B drugs should have been the lower of the AWP (or 95%AWP or 85% AWP) and the EAC (= ASP), regardless of whether the AWP exceeded the yardstick spread of 30%.

¹³ I discuss how much HCFA and Medicare knew in Section II.C below.

¹⁴ Joint Motion, p. 10.

Plaintiffs' construction of the relevant Medicare statute as implemented in my damage analysis for that period of time (indeed for all periods during the Damage Period in which the Statute was revised) is based upon Statute, as cited in footnote 13 of my December 15, 2005 Liability Declaration. This construction is not "inconsistent with HCFA's interpretation;" it implements it explicitly. The Statute reads:

"Payment for a drug ... is based on the lower of the estimated acquisition cost (EAC) or the national average wholesale price [i.e., AWP]¹⁵ of the drug. ... For multiple-source drugs, payment is based on the lower of the estimated acquisition cost ... or the wholesale price that, for this purpose, is defined as the median price for all sources of the generic form of the drug." (Source: 42 CFR 405.517, Revised October 1, 1996; emphasis added)

Contrary to Defendants' assertion,¹⁶ Plaintiffs do understand the fact that "HCFA has always interpreted AWP to mean something different than ASP." Indeed, my formulaic methodology explicitly incorporates into the calculation of damages the fact that AWPs exceed ASPs, hence EACs. Liability is alleged not because AWP exceeds the ASP; rather liability is alleged because it exceeded ASP by the unreasonably and unexpectedly substantial amounts reflected in the "mega-spreads" recognized by Judge Saris and Dr. Berndt. Once liability is determined, damages occur precisely because reimbursement occurred at the higher of the artificially inflated AWP rather than "the lower of the EAC and or the national average wholesale price [AWP] of the drug." The Judge has agreed with this interpretation of the economic implications of the Statute.¹⁷

9. Indeed, individual Defendants recognize that my formulaic methodology admits to the fact that AWP exceeds ASP and that it implements damage calculations only when

¹⁵ Note that the average wholesale price (AWP) does appear in the 1991 statutory revision, as is recognized in Defendants' *Joint Motion* (pp. 4, 9). The fact that the *Joint Motion* states that "AWP appeared in the Medicare statute for the first time in 1997" on page 12 is contradictory and must be a typographical error. Note further that Defendants feebly attempt (at p. 12 of their *Joint Motion*) to imply that "the statute did not include an express definition of the term [AWP]." This innuendo does not work. Regardless of the "express definition," the industry has had a very definite understanding of AWP throughout the Damage Period; indeed, Defendants quote (*Joint Motion* at p. 13): "A House Report ... stated 'The AWPs are reported by drug manufacturers to organizations that publish the data in compendia."

Neither I nor the Plaintiffs disagree with this characterization.

¹⁶ Joint Motion, pp. 11-12.

¹⁷ At pp. 58-59 of the *Memorandum and Order*, Judge Saris states for Sub-Class 1: "The Court is satisfied that as to the Medicare Part B beneficiary class, a class action is a superior method to resolve the dispute. Defendants have not identified any plausible individual issues that will arise with regard to these class members other than their proofs of damages, which may entail reviewing documents to determine whether each patient was required to pay a percentage-based co-pay and whether each has supplemental insurance. These damages calculations will be largely formulaic. Even if some corroboration and individualized attention is necessary, it is unrealistic to expect millions of beneficiaries across the nation to repeatedly prove these claims. The number of drugs at issue in the Medicare Part B context is limited to about seventeen, so even if deciding spreads by individual NDCs is necessary, it would not be unmanageable" (emphasis added). For Sub-Class 2, she states: "Again, the common factual issues (as outlined in the previous section) predominate, in that the TPPs are required by contract to supplement Medicare drug co-payments" (emphases added).

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In Re:

PHARMACEUTICAL INDUSTRY

AVERAGE WHOLESALE PRICE

LITIGATION

) CA No. 01-12257-PBS

MDL No. 1456

Pages 10-1 - 10-149

BENCH TRIAL - DAY TEN

BEFORE THE HONORABLE PATTI B. SARIS UNITED STATES DISTRICT JUDGE

United States District Court 1 Courthouse Way, Courtroom 19 Boston, Massachusetts November 27, 2006, 9:10 a.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

- 1 Q. So, in your view, there's nothing inherently wrong with
- a published AWP that is different from the actual selling
- 3 price of the drug, right?
- 4 A. Well, again, I'm not an expert on right and wrong, but
- 5 the general issue is that they should track but not certainly
- 6 equal.
- Q. Your problem with it is when the spread becomes too big,
- 8 right?
- ⁹ A. Yes.
- 10 Q. But you don't have a specific opinion as to whether
- Dr. Hartman's 30 percent spread is the right yardstick,
- 12 correct?
- 13 A. That's correct.
- 14 THE COURT: Do you believe that all the third-party
- payors throughout the class period knew about the formulaic
- 16 20 to 25 percent markup between WAC and AWP?
- THE WITNESS: I believe the relationship between
- those list prices, I believe that that was generally known.
- 19 I'm sure that not universally known, but I believe that that
- 20 information --
- THE COURT: I'm not talking about the consumers.
- THE WITNESS: Right, right, no, no, of course.
- THE COURT: But the third-party payors, was that
- just universally known throughout the class period?
- THE WITNESS: I believe, for those that worked in

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In Re:

PHARMACEUTICAL INDUSTRY

AVERAGE WHOLESALE PRICE

LITIGATION

) CA No. 01-12257-PBS

MDL No. 1456

Pages 9-1 - 9-144

BENCH TRIAL - DAY NINE

BEFORE THE HONORABLE PATTI B. SARIS UNITED STATES DISTRICT JUDGE

United States District Court 1 Courthouse Way, Courtroom 19 Boston, Massachusetts November 21, 2006, 9:10 a.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

- United States, and so if that's what you mean by it works.
- Q. No, she said it works, it works because for 99 percent
- of the drugs, there's a predictable relationship between AWP
- 4 and ASP. You agree with that, don't you?
- 5 A. I haven't analyzed that to come up with a number.
- Okay, you believe AWP works for drugs where there's a
- spread between AWP and ASP that's 30 percent or less, right?
- 8 A. I agree that the AWP system as it's evolved has led to
- 9 certain understandings about spread, and it's been working,
- but it's clearly been in need of some change that we've seen
- in the MMA.
- Q. But your theory is that you were looking for drugs where
- there was a predictable relationship between AWP and ASP,
- 14 correct?
- A. Are we talking about the comparator drugs? Are you
- 16 saying --
- 17 Q. No, your analysis here, your expectation analysis, what
- you were looking for is, was there a predictable
- relationship? And your yardstick is 30 percent, right?
- 20 A. I'm saying, given that I find a predictable relationship
- for classes of drugs and reflected in expectations, that's
- what I -- I'm finding payors either understood or just
- basically took as for granted.
- Q. All right. So let's talk about Procrit. Now, for
- Procrit, early on in the case you thought 16 of the 114 NDCs

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In Re:

PHARMACEUTICAL INDUSTRY

AVERAGE WHOLESALE PRICE

LITIGATION

) CA No. 01-12257-PBS

MDL No. 1456

) Pages 8-1 - 8-175

BENCH TRIAL - DAY EIGHT

BEFORE THE HONORABLE PATTI B. SARIS UNITED STATES DISTRICT JUDGE

United States District Court 1 Courthouse Way, Courtroom 19 Boston, Massachusetts November 20, 2006, 9:15 a.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

- THE COURT: If you wanted to look at the
- ² deposition.
- THE WITNESS: Oh, I see, I do have it in front of
- 4 me. The amending to my response made it a bit broader.
- 5 Counsel said because the "entire" industry knows that it
- doesn't. I think my response was that "Because the industry
- 7 knows that it doesn't."
- Now, by the industry here, I'm certainly referring
- ⁹ to the manufacturers. It's certainly clear that I've
- testified that some payors did not know that fact. So the
- industry generally knows that. I wouldn't -- this is not the
- law of gravity or the speed of light.
- Q. Well, take a look at Page 672, the testimony that begins
- at Line 7: "Question: Well, you keep referring to a market
- 15 understanding. Do you have any reason to believe that the
- government doesn't have the same understanding? Answer: The
- government has -- you need to be more -- well, let me answer
- this briefly.
- "The government has set reimbursement rates that
- reflect an understanding that is comparable to what I would
- say is the -- in my yardsticks."
- Was that testimony true when you gave it?
- 23 A. That testimony, what I'm saying there is that the
- government -- there are studies that I've cited in my direct
- testimony here and that I've reviewed earlier before this

- deposition that showed relationships between AWP and ASP that
- were reflected in Medicare's movement toward 95 percent and
- 3 85 percent that showed some -- that showed some understanding
- of the relationship of AWP to ASP, but that's as far as I
- 5 take it.
- 6 Q. You say the understanding of the government was
- 7 comparable to what you said in your yardsticks, and your
- yardstick was a 30 percent expectation yardstick, correct?
- 9 A. I set a threshold yardstick of 30 percent. I looked for
- reimbursement yardsticks, measures of what were negotiated,
- and all of those -- those included the manufacturers that I
- looked at, they included the studies that I reviewed, and
- they included the contracts that I reviewed. And so that's
- the body of yardsticks or the sample of yardsticks. Finally,
- 15 I set a threshold that was conservative for all the
- yardsticks I saw.
- Q. And you applied that 30 percent yardstick to Medicare in
- 18 your December 15, 2005 expert report; isn't that true?
- 19 A. That's correct.
- THE COURT: And why did you do it then? Put aside
- the legal question for a minute. Did you think it was fairly
- 22 applicable to them?
- THE WITNESS: Actually I didn't know. I mean, I
- was asked to do it as a -- I was told, look, there's legal
- arguments going on both sides. That's why there was a

- supplemental to the original declaration. And so I set that
- 2 as a conservative threshold --
- THE COURT: Well, would it be one reasonable way to
- 4 consider damages if I said there was no strict liability?
- 5 THE WITNESS: Well, there are many ways that one
- 6 could come at it. Is that one way? It could be one of a
- 7 variety of ways. I guess I'd want to --
- THE COURT: So, in other words, if I don't go with
- 9 the strict liability -- and I understand some case law I
- think they're referring to -- but if I went more along the
- standard of what's unfair or deceitful, I need to understand
- what was understood in the market. So would the 30 percent
- 13 yardstick be one fair way of thinking about what Medicare
- 14 knew in the market?
- THE WITNESS: Well, it's a very conservative
- threshold for what was a range of reimbursement rates that I
- 17 find in the market.
- THE COURT: Just as it is with the other one, the
- 19 Class 3?
- THE WITNESS: That's right.
- Q. And you base that 30 percent threshold for Medicare in
- your initial report on an economic analysis, correct?
- 23 A. My entire expert report was the implementation of
- economic formulations and economic analysis at the direction
- of certain assumptions regarding legal issues.

DAY 39

1	UNITED STATES DISTRICT COURT
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	ALAN MACKENZIE, JANICE
7	SWIRSKI, HENRY VAN MOURIK, *
•	DONNA TOM, DONALD PATTON, *
	DONNA 10M, DONALD INITION,
8	DONALD MEEK, ERIC OTTERBEIN *
	RITA JOKIAHO, CAREY SMITH, *
9	MARK SMITH *
,	Defendants *
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	BEFORE THE HONORABLE DOUGLAS P. WOODLOCK
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-	JURY TRIAL - DAY 39
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1	APPEARANCES:
2	MICHAEL K. LOUCKS, ESQ. Chief, Health Care
_	Fraud Unit, GEORGE W. VIEN, ESQ., and SUSAN G.
~	WINKLER, ESQ., Assistant United States Attorneys,
3	WINNER, EDV., ADDIDENT OFFICE BEAUTY Chita
	U.S. Attorney's Office, 1 Courthouse Way, Suite
4	9200, Boston, Massachusetts 02210, on behalf of

the United States

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designed to induce higher volume purchases. And the
      marketing of that, there was extensive testimony about
      that.
                THE COURT: All right. No. it's not a
      question of the marketing. It's the question of -- from
      my perspective -- what do I tell the jury about this?
                MR. MONICO: Your Honor, may I just say
      something?
                THE COURT: Sure.
                MR. MONICO: It just strikes me as amazing
      that the Government, everytime they talk about there's a
      discount, if the discount was intended to induce a sale.
      How could a discount ever not be intended to induce a
      sale?
                THE COURT: Of course.
                MR. MONICO: It strikes me so absurd, that
      they keep saying that if that happens, then these other
      things apply. So, I mean it sounds like -- that strikes
      me --
                THE COURT: That's precisely the argument the
      Government is making. I understand. All right.
21
                MR. LOUCKS: That's precisely the argument
      we are making, Your Honor. And the reason why the
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      reporting obligation and informing the buyer is
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important is because the Medicare program was set up as

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the lesser of cost or charges. And where there are discounts, the cost is lower. And the Medicare program didn't require when there's a safe harbor --THE COURT: That's true of acquisition price as well, regular acquisition price. MR. LOUCKS: It is. But if the Medicare program gets regular reports of discounts from physicians, you can take a look at what it's paying and say "we're paying way too much." THE COURT: I don't disagree with that. MR. LOUCKS: And that's the reason for the safe harbors. THE COURT: And that's why I keep asking this question about what's the duty to disclose. That's why I want to -- the principal reason why I want to focus on

that. But it's the odd situation that it's only if you do a discount. If by contrast, you have the same price for whatever quantity you have, there is no obligation to report that to the Government. MR. LOUCKS: If I have a list price and you

make no discounts, right.

THE COURT: Right.

MR. LOUCKS: As a matter of fact, Your Honor,

a historical fact here, not proven to this jury, but 24 everybody got the spread between AWP and list price, the 25

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same 25 percent, whether it was Zoladex or Lupron or some other oncology drug, until, we think, this group came up with the Return to Practice inducements. The extra volume discount. And the 25 percent, everyone gets that. That's there. That's what Congress expected with AWP.

THE COURT: Well, I understand that. So, now with specificity and maybe duplication, you're going to focus me on precisely the language of the obligation.

Account reviews. Any question that if offered as a quid pro quo, that constitutes a kickback? MR. KETTLEWELL: Well, I think there is a

question there, Your Honor. I don't think there is any independent substantial value in an account review with a customer. And interestingly, the OIG observed just that. It's a legitimate sales support. We will offer up a jury instruction along that line. But we believe it's completely legitimate sales support that a company can give to its product. If you listen to Elaine

Morgan, who was the only witness who testified about the 21 limited account reviews done in the mid-Atlantic region, 22

she testified that the accounts she went into were 23

accounts that were having trouble paying TAP. And the 24 25

reason she went in was so that the doctors can get

reimbursed so they could pay their bills. And that more or less proves, I think, what we are saying, that the

account reviews were offered and the value of them primarily was to TAP and not to the customer.

THE COURT: All right.

MS. WINKLER: The answer to that was Phil Beard's testimony who said that he, as an independent consultant, went out and provided such services at whatever his rate was.

THE COURT: Well, but independent consultant is a little different. What we're talking about here is account review.

MS. WINKLER: Is a business value -- if we're talking about those accounts where they went in and they did the reimbursement review, there is an independent financial value of that. It's a business part of running your medical practice. And if it's a quid pro quo for business, if it's to keep the Lupron business, then it's a kickback.

THE COURT: Well, let me just focus this a bit

2-1

Page 1

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In Re:
PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

OCA No. 01-12257-PBS
MDL No. 1456
Pages 2-1 - 2-204

BENCH TRIAL - DAY TWO

BEFORE THE HONORABLE PATTI B. SARIS UNITED STATES DISTRICT JUDGE

United States District Court 1 Courthouse Way, Courtroom 19 Boston, Massachusetts November 7, 2006, 9:15 a.m.

LEE A. MARZILLI and TIMOTHY J. WILLETTE
OFFICIAL COURT REPORTERS
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

- names of any of them?
- THE WITNESS: The Zofran, that one I remembered. I
- remembered seeing that on my papers. That's the only one
- 4 that I really remembered offhand.
- 5 THE COURT: Thank you.
- THE WITNESS: You're welcome.
- 7 Q. And you likewise don't know who manufactured the drugs
- 8 that you were administered, correct?
- 9 A. I'm sorry?
- 10 Q. You likewise don't know who manufactured the drugs that
- 11 you were administered; is that right?
- 12 A. No, I don't.
- 13 Q. Prior to becoming involved in this litigation, did you
- have any knowledge regarding what AWP meant?
- 15 A. No.
- 16 Q. When you got involved in this case, you were provided a
- copy of plaintiff's complaint; isn't that correct?
- 18 A. Yes, ma'am.
- 19 Q. And prior to becoming involved in this litigation, were
- you aware of any of the facts that were alleged in that
- 21 complaint?
- 22 A. No, I wasn't.
- O. In connection with executing your trial affidavit in
- this case, you were provided with some documents from your
- lawyers as well, weren't you?

- deductible obligation at that point in time?
- 2 A. No.
- MR. HAVILAND: Your Honor, our proffer was very
- narrow, but we're happy to submit supplemental exhibits that
- 5 clear up some of the factual issues that I think are probably
- troubling the Court at this point in time given the witness's
- 7 unavailability to talk about specific issues, but I'd like to
- 9 just conclude.
- 9 BY MR. HAVILAND:
- 10 Q. Now, Mrs. Hopkins, the two times that you treated with
- these drugs for your cancer, yesterday counsel for BMS said
- that everybody in the world knew certain things about their
- conduct, and I'd like to know from you:
- At the time you treated and paid these bills, did
- you know that the AWPs were inflated for the drugs you were
- 16 taking?
- A. No, I did not.
- 18 Q. Did you know --
- MR. SWEENEY: Objection, your Honor. There's no
- evidence in the record that the AWP was charged for any of
- these drugs. The witness hasn't testified to that. She's
- not competent to testify --
- THE COURT: Overruled. Did you know anything about
- 24 AWP at all?
- THE WITNESS: No, I did not.

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Young, Larry (2005-11-9) HIGHLY CONFIDENTIAL Oklahoma City, OK

November 9, 2005

		Page 1
IN THE UNITED STATES	DISTRICT COURT	
FOR THE DISTRICT OF	MASSACHUSETTS	
* *	* * *	
IN RE: PHARMACEUTICAL INDUSTRY)	
AVERAGE WHOLESALE PRICE)	
LITIGATION) MDL DOCKET NO.	
) CIVIL ACTION	
)) 01CV12257-PBS	
D))	·
THIS DOCUMENT RELATES TO:)	
ALL ACTIONS)	
)	
D))	
* * * *	*	
HIGHLY CONFI	DENTIAL	
DEPOSITION OF L	ARRY YOUNG	
TAKEN ON BEHALF OF	THE DEFENDANTS	
ON NOVEMBER 9, 2005, BEGI	NNING AT 10:06 A.M.	
IN OKLAHOMA CITY		

REPORTED BY: JANE McCONNELL, CSR, RPR, RMR, CRR

Young, Larry (2005-11-9) HIGHLY CONFIDENTIAL Oklahoma City, OK

November 9, 2005

	Page 61
1	whether plaintiffs in this action are claiming that
. 2	the pharmaceutical manufacturers committed
3	fraud?
4	A No.
5	Q Do you think the pharmaceutical
. 6	manufacturers committed fraud, committed fraud
7	in connection with the pricing of their drugs?
8	MR. WILLIAMS: Objection, lack of
9	foundation, calls for speculation.
10	A I don't know.
11	Q (BY MR. YOUNG) Prior to reading the
12	Complaint, had you ever heard of the term average
13	wholesale price or AWP before?
14	A No.
15	Q Have you done any additional research on
16	what average wholesale price or AWP is aside from
17	any communication with your attorneys?
18	A No.
19	Q Do you know how AWP is calculated?
20	A No.
21	Q Do you know who calculates AWP?
22	A No.

Shepley, James E. (2005-11-11)

November 11, 2005

Reno, NV

Page 1

UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS -000-

IN RE PHARMACEUTICAL MDL No. 1456

INDUSTRY AVERAGE PRICE

LITIGATION

CIVIL ACTION: 01-CV-12257-PBS

Judge Patti B. Saris

DEPOSITION OF

JAMES E. SHEPLEY

Friday, November 11, 2005

Reno, Nevada

Reported by: Lesley A. Clarkson, CCR #182

Reno, NV

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Page 29
     sorry, we were talking.
2
               MR. HAVILAND: Yes.
               MS. LAWSON: Let's take a two-minute break
     while they bring in coffee.
5
                          (Off the record.)
 6
               MS. LAWSON: Back on the record.
     BY MS. LAWSON:
               Are you familiar with the term "average
     wholesale price"?
10
          Α
               No.
11
               Just to make that clear, you said you are
12
     not familiar with the term "average wholesale
13
     price"; is that correct?
14
          А
               Yes.
15
               Are you familiar with the term "wholesale
16
     acquisition cost"?
17
          Α
               No.
               Are there other drugs that, other than
18
     Lupron, that a doctor has given to you?
19
20
               Prescribed?
          Α
21
               No, let's, we will clarify here. I'm not
22
     asking just about, I'm not asking about someone
```

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IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In Re:
PHARMACEUTICAL INDUSTRY
AVERAGE WHOLESALE PRICE
LITIGATION

) CA No. 01-12257-PBS
) MDL No. 1456
) Pages 17-1 - 17-132

BENCH TRIAL - DAY SEVENTEEN

BEFORE THE HONORABLE PATTI B. SARIS UNITED STATES DISTRICT JUDGE

United States District Court 1 Courthouse Way, Courtroom 19 Boston, Massachusetts December 11, 2006, 9:15 a.m.

TIMOTHY J. WILLETTE, RDR, CRR
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617) 345-6787

- Q. And do you see for the two Johnson & Johnson products,
- 2 Procrit and Remicade, am I correct, Dr. Hartman, that if the
- 3 Court for Class 2 were to apply a 30 percent liability
- threshold, there would be zero damages for Procrit and
- 5 Remicade?
- 6 A. That's correct.
- 7 . Q. And am I also correct that you use the same ASPs and
- 8 AWPs for all three classes which the Court has certified?
- 9 A. I think that's correct.
- 10 Q. So the same spreads apply to all three classes, correct?
- 11 A. The spreads from the AWP to the ASPs apply to all the
- classes. The one -- there's a distinction in Class 2 damages
- here in that over portions of the period, the reimbursement
- rate was at a percentage below AWP, so that would be a reason
- why even though the spread may be above, say, 30 percent for
- 16 Class 3, for Class 2, when you're looking at reimbursement at
- 95 percent of AWP, you've got to take that into account in
- whatever comparison you're making.
- 19 Q. All right. If we could turn to 4007, please, and if you
- 20 would turn to the Procrit page.
- 21 A. I'm sorry. I'm just getting it.
- I'm there.
- Q. Now, you state here -- well, did you actually prepare
- 24 this chart?
- 25 A. I had my staff prepare this chart.

IN THE UNITED STATES DISTRICT COURT FOR THE DISTRICT OF MASSACHUSETTS

In Re:

PHARMACEUTICAL INDUSTRY

AVERAGE WHOLESALE PRICE

LITIGATION

) CA No. 01-12257-PBS

MDL No. 1456

) Pages 12-1 - 12-144

BENCH TRIAL - DAY TWELVE

BEFORE THE HONORABLE PATTI B. SARIS UNITED STATES DISTRICT JUDGE

United States District Court 1 Courthouse Way, Courtroom 19 Boston, Massachusetts November 29, 2006, 9:10 a.m.

LEE A. MARZILLI
OFFICIAL COURT REPORTER
United States District Court
1 Courthouse Way, Room 3205
Boston, MA 02210
(617)345-6787

- 1 Q. Or Blue Cross-Blue Shield, right?
- 2 A. I agree, and I think, again, that's not the relevant
- question. These individual Medicare beneficiaries are in
- some sense protected by Medicare. I mean, they don't go in
- and choose the amount of their reimbursement. It's set by
- 6 Medicare, and in the same way the Taft-Hartley funds are
- 7 under the umbrella of Blue Cross-Blue Shield and other big
- ⁸ payors.
- 9 Q. Well, the information might also, as you pointed out,
- change over time. You might have more information about one
- drug rather than another; you might have more information at
- one point in time than another, correct?
- 13 A. Yes.
- Q. Okay. Indeed, isn't it fair to say that the information
- that you've looked at that shows some spreads isn't the only
- information that was available to people in the marketplace?
- You haven't canvassed in your direct examination, or even all
- your prior reports, all the information that was available to
- people one way or another?
- 20 A. I don't know how I would know that I've got it all.
- 21 I've got a substantial amount canvassed.
- Q. Well, in your direct testimony, did you, for instance,
- provide to us what First Databank said AWP meant during the
- class period? Yes or no, did you provide it?
- 25 A. I didn't provide that.